UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,
ex rel. JOHN R BORZILLERI, M.D. et al.,

Plaintiffs,

vs.

ABBVIE, INC., et al.,

Defendants.

Case No. 15-cv-7881(JMF)

MEMORANDUM OF LAW IN SUPPORT OF RELATOR'S OPPOSITION TO UNITED STATES' MOTION TO DISMISS PURSUANT TO 31 U.S.C. § 3730(c)(2)(A)

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In accordance with the Court's order dated November 16, 2018, relator, John R. Borzilleri, M.D., respectfully submits this memorandum of law in support of his opposition to the United States' (the "Government's") 31 U.S.C. § 3730 (c)(2)(A) motion to dismiss this *qui tam* action, filed as per the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*

PRELIMINARY STATEMENT

In this *qui tam* action, the Relator, John R. Borzilleri, M.D., has alleged, in detail and with specificity, that the Manufacturer and PBM Defendants have caused severe patient and taxpayer harm through brand drug price inflation, driven by a straightforward, fraudulent "service fee" scheme in the Medicare Part D program. SAC ¶¶ 12-13. There is nothing subtle or complicated about the scheme. For the Defendant parties, Part D profits related to the specific Defendant products have been driven almost entirely by four-to-six-fold price increases over the past decade, while clinical use of the drugs by Part D beneficiaries has plummeted, eroded or stagnated. SAC ¶¶ 2, 31. These abusive fee arrangements are standardly calculated, by contract, as a "percent" of "list" prices and severe price increases, with no relation to services being provided or legitimate fair market value (FMV) compensation as required by law. SAC ¶ 26. Furthermore, recent Centers of Medicare and Medicaid Services (CMS) Part D data and Defendant public disclosures have definitively established the fraudulent "service fee" scheme, as the only explanation for anti-competitive Defendant drug product price increases. Southern District of New York (SDNY) Rel Opposition ("Opp.") ¶¶ pages 3, 45-50.

The Relator avers that price increases directly caused by the ongoing scheme, just for the 14 specific Defendant drugs in this SDNY action, have already caused more than $35 billion in fraudulent billing to taxpayers in Medicare Part D over the past decade. SAC ¶ 92. In Relator's District of Rhode Island (D-RI) *qui tam* action, he alleges fraudulent Part D drug spending for the 8 Defendant multiple sclerosis (MS) drugs at more than $18 billion since the program began. D-RI SAC ¶ 24. Relator's D-RI SAC is provided as Exhibit 1. Many American patients have lost their lives, lost access to drugs

and/or faced financial ruin directly resulting from the scheme. SAC ¶ 22.

Notably, neither the Government's nor the Defendants' motions to dismiss, in either SDNY or D-RI, attempt to factually challenge the Relator's well-pleaded allegations. With these allegations "assumed true" at this stage, on this basis alone, the Court should expeditiously deny the Government's motion to dismiss to prevent further disruption and delay in Court proceedings.

Relator avers that the Government's eleventh-hour, meritless and disruptive motion should be denied outright without need for a hearing. Supported by Declaration, Dr. Borzilleri will highlight long-standing public interest concerns regarding the Government's investigation of these *qui tam* matters. See Relator John R. Borzilleri, M.D.'s Declaration, dated January 11, 2019. ("Borzilleri Decl.") The Government's oddly-timed motion to dismiss is consistent with "pretextual, arbitrary and capricious" behavior regarding these *qui tam* cases over the past several years. If the Government's motion is not outright denied by the Court, Relator requests additional briefing, discovery and an evidentiary hearing, which is supported by Second Circuit precedent.

SUMMARY

Contrary to government claims, Relator's *qui tam* cases are: (1) remarkably straightforward, factually well-supported and meritorious; (2) exposing unprecedented patient and taxpayer harm; and, (3) merit a judicious use of government resources, with a vast opportunity for restitution for the government and for taxpayers. Given the vast taxpayer harm alleged by Relator, it is hard to fathom how the Government could argue for dismissal based upon "resources", without providing the Court substantive arguments in its motion regarding its claim that the cases "lack merit". However, that is exactly the Government's position.

Furthermore, the physician Relator is surprised to see the Government co-opt the Defendants' ad hominem personal attacks as a basis for dismissal, largely based upon unsubstantiated allegations in ongoing unrelated employment termination litigation. This Government tact is particularly

disappointing since DOJ is well-aware of the Relator's extraordinary efforts over the past five-plus years, in the public interest, to both address the escalating US drug pricing crisis and to assist and accelerate the government's investigation of his cases.

Relator has had longstanding concerns regarding the Government's investigation and decision-making related to his *qui tam* actions. In fact, based upon extensive interactions with DOJ over the past five-plus years (as set forth in his Declaration), the Relator avers that the Government failed to intervene in these matters despite its verification of the scheme. In addition, the Government failed to pursue key allegations, evidence and witnesses prior to its non-intervention decisions. Due to Dr. Borzilleri's public interest concerns, he began challenging DOJ requests for investigation extensions from Court in both jurisdictions in 2017. In its current motion, DOJ now ignores major new evidence provided in Relator's briefing, which has arisen since the Government ceased investigation in March 2018. First, the two leading PBM Defendants, Express Scripts and CVS Health, recently publicly admitted for the first time that a very small share of their profits now come from "manufacturer rebates", leaving "manufacturer service fees" (linked to vast price increases) as the only path for significant PBM profits related to the Defendant products in Part D. Opp. ¶ page 3. Second, newly public Medicare Part D data verifies extreme anti-competitive growth in taxpayer spending for the Defendant drugs, driven entirely by price increases and the scheme. Opp. ¶¶ pages 3, 45-50.

Relator has had no investigative interaction with the Department of Justice (DOJ) in either jurisdiction since its March 2018 non-intervention decisions and there is no indication that the government considered Relator's new evidence in its late-dated decision to seek dismissal.

The Government's motion should be denied regardless of the 31 U.S.C. § 3730 (c)(2)(A) standard of review. The Government's request for rote application of the *Swift* "unfettered discretion" standard from the D.C. Circuit is inappropriate and against the public interest. In fact, *Swift* itself recognizes the role of judicial review when fraud on the part of the government is a strong possibility.

Swift v. United States, 318 F.3d 250 (D.C. Cir. 2003). Further, a recent Second Circuit precedent supports judicial review, if there is a "strong showing" of pretext or bad faith on the part of agency decision-makers". *State of New York, et al., v. United States Department of Commerce*, 215 (SDNY, July 26, 2018).

Using the *Sequoia Orange* standard from the Ninth Circuit, the Government's motion should also be denied due to the lack of a "valid government purpose". *U.S. ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998). Given the unchallenged, well-supported merits of Relator's case and massive financial fraud estimates, government concerns regarding its resource and financial burden from ongoing litigation are unsupportable. The government overstates the "complexity" of Relator's *qui tam* cases. As per briefing, the cases are remarkably straightforward which enables targeted discovery and the efficient use of Government resources. SAC ¶¶ 11, 169.

If the Court accepts the Government's *Sequoia Orange* rationale, judicial review is warranted to due to Relator's extensive evidence, supported by Declaration, that the government's dismissal attempt is "fraudulent, arbitrary, capricious and illegal".

PROCEDURAL HISTORY

Relator filed this FCA *qui tam* action on October 6, 2015, after having filed an earlier *qui tam* action, *U.S. ex rel. Borzilleri v. Bayer et al*, 14-CV-031-WES-LDA, in the D-RI. In both cases, the Relator alleges that the Pharmaceutical and PBM Defendants have violated both the Anti-Kickback Statue (AKS) and the False Claims Act (FCA) through a price collusion scheme pertaining to "service fees" in the Medicare Part D program.

In March 2018, the Government declined to intervene in both the SDNY and the D-RI *qui tam* cases. In April 2018, both cases were unsealed. On October 1, 2018, the SDNY Defendants moved to dismiss this action. On November 19, 2018, Relator filed his opposition to the Defendants' motions. Also, on November 19, 2018, the RI Defendants filed motions seeking dismissal of Relator's *qui tam*

action. The SDNY Defendants filed their replies on January 4, 2019. The Relator's opposition to the RI Defendants' motions is due by February 16, 2019. Coincident with the current SDNY motion, the Government filed a similar motion seeking dismissal of Relator's D-RI case.

Contrary to the Government's claims in its motions to dismiss, there are important distinctions between the pending SDNY and RI actions. Relator's initial RI action focused solely on the narrow US "specialty" drug market, which accounts for only 1-2% of annual US pharmaceutical prescriptions. The Relator's second *qui tam* filing in SDNY provided the Government with unique notice of expansion of the systemic "service fee" scheme into the far broader US market for "traditional" pharmaceutical products. In the U.S., "traditional" brand drugs account for ten times the prescription volume and treated patients compared to "specialty" drugs. In the SDNY action, several of the key Defendant "traditional" drugs, are among the most widely-used Part D brand drugs. See Opp., page 46. In the near term, Relator plans to file a motion seeking discovery and an evidentiary hearing to address first-to-file issues in this SDNY action.

THE LEGAL STANDARD FOR 31 U.S.C. § 3730(c)(2)(A) DISMISSAL

A. The *Swift* and *Sequoia Orange* Standards – Judicial Review Appropriate with Both.

The Second Circuit, and most federal circuit courts, have yet to decide on the standard for dismissal under § 3730(c)(2)(A). In two circuits, appellate courts have articulated two different standards. In the D.C. Circuit, the Court recognized the Government's "unfettered right" to dismiss a *qui tam* action - the *Swift* standard. *Swift v. United States*, 318 F.3d 250 (D.C. Cir. 2003). In an earlier decision, the Ninth Circuit applied a "rational relation test" for dismissal, but still recognized the Government's broad prosecutorial discretion to dismiss even meritorious *qui tam* cases so long as the reasons for dismissal are rationally related to a legitimate government interest – the *Sequoia Orange* standard. *U.S. ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.,* 151 F.3d 1139 (9th Cir. 1998).

Both standards recognize the Government's broad right to seek dismissal of a *qui tam*

action based on § 3730(c)(2)(A), over the Relator's objections. "After all, a *qui tam* action is brought in the Government's name and, as the real party of interest, it should have broad discretion to determine its fate." *Ridenour,* 397 F.3d at 937 (quoting *United States ex rel. Sequoia Orange Co. v. Suniand Packing House Co.,* 912 F.Supp. 1325, 1341 (E.D.Ca. 1995).

However, both *Swift* and *Sequoia Orange* also recognize that unique situations arise in which "unfettered dismissal" of a *qui tam* action by the Government should not be allowed, without greater review by the Court. "The *Swift* court indicated there might be exceptions to unfettered government discretion to dismiss a *qui tam* action as, for example, where fraud on the court is alleged". *Ridenour v. Kaiser-Hill Co., LLC*, 397 F.3d 925 (10th Cir. 2005). In fact, the Government conceded this fact during oral arguments for *Swift*. "There may be an "exception for fraud on the court". S*ee also Hoyte v. Am. Nat'l Red Cross*, 518 F.3d 61, 65 (D.C. Cir. 2008). In *Sequoia Orange*, the Ninth Circuit established a higher bar for Government dismissal under § 3730(c)(2)(A), concluding that a judicial role "does not contravene separation of powers principles". "Ample precedent exists for judicial oversight of the government's decision to dismiss a qui tam action".

The *Sequoia Orange* requires a "two step analysis" to test the justification for dismissal: (1) identification of a valid government purpose; and (2) a rational relation between dismissal and accomplishment of the purpose." 912 F.Supp. at 1341. If the government satisfies the two-step test, the burden switches to the relator "to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal." Id. at 1347.[1]

B. A Recent Ninth Circuit Ruling in Favor of Relator, Based on *Sequoia Orange*.

On June 29, 2018, in *U.S., ex rel. Thrower v. Academy*, the Court denied the §

[1] *Sequoia Orange* draws significant support from the legislative history of the False Claims Act: Amendments Act of 1986 "provides *qui tam* plaintiffs with a more direct role ... in acting as a check that the Government does not neglect evidence, cause undue delay, or drop the false claims case without legitimate reason." S.Rep. No. 99-345, at 25-26 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5291.

3730(c)(2)(A) motion to dismiss, due to Government's failure to fully investigate Relator's allegations and its failure to submit evidence in response to the Court's order. *United States of American, ex rel. Thrower v. Academy Mortgage Corporation*, No. 16-cv-02120-EMC (N.D. Cal., June 29, 2018). On October 3, 2018, the Court denied the government's motion to stay the *Thrower v. Academy* proceedings due to its failure to establish "a substantial case for relief on the merits". *supra,* (October 3, 2018).

C. In *Swift*, Both D.C. Courts Considered *Sequoia Orange* and Case-specific Factors.

The Government's view of "unfettered discretion" in this matter is inconsistent with the D.C Circuit and Appellate Courts' own decisions – in *Swift*, both Courts considered the broader *Sequoia Orange* standard, as well case-specific factors.[2]

D. Based on *Swift,* Discovery from the Government is Appropriate in these *QT* cases.

Contrary to the current Government view, the D.C. Appellate in *Swift* recognized the role of judicial review in § 3730(c)(2)(A) dismissals.

Furthermore, citing *Swift*, a recent case in the Fourth Circuit provides support for judicial review and limited discovery pertaining to a Government § 3730(c)(2)(A) motion. "…Relator should be able to review evidence relied upon by plaintiff to discover whether material information was missed or misinterpreted in Plaintiff's review of evidence. Further, Relator should have the opportunity to discover evidence indicative of improper decision-making, including evidence of bad faith, abuse of discretion, fraud, arbitrary or capricious decision-making and other illegal activity." *United States ex rel. Vincent J. Stovall v. Webster University.*, No. 15-cv-03530-DCC (D. S.C. April 4, 2018).

Despite *Swift's* clear support of appropriate judicial review, the Government requests that

[2] *Swift* alleged relatively miniscule harm of $6,169.20, related to allegations of fraudulent time sheets and leave slips for three current and former Justice Department employees.

the Second Circuit adopt a new blanket standard for "unfettered" executive prosecutorial discretion. This request should be denied.

E. Both *Swift* and *Sequoia Orange*, and Case-Specific Factors, are Standardly Reviewed by the Courts, including the First and Second Circuit.

Without clear standards, it is not surprising that most federal circuits, including the First and the Second Circuits, have taken a measured and flexible approach to the review of § 3730(c)(2)(A) *qui tam* dismissals, including consideration of both *Swift* and *Sequoia Orange*, as well as case-specific factors. In *Amico*, the Court states: "The Second Circuit, for its part, has not decided the proper standard to be applied, but has cited the *Sequoia* standard with approval, albeit in *dictum* in a case reversed on other grounds by the Supreme Court, *U.S. ex rel. Stevens v. Vt. Agency of Natural Res.*, 162 F.3d 195, 201 (2d Cir. 1998), *rev'd on other grounds*, 529 U.S. 765 (2000). *U.S. ex rel. Amico v. Citigroup, Inc.*, No. 14-CV-4370 (CS) (S.D.N.Y. Jun. 8, 2015). Since *Stevens*, at least one court in this Circuit has found the *Swift* standard the more persuasive of the two. *See U.S. ex. rel. Piacentile et al. v. Amgen Inc.*, 2013 WL 5460640, at *2-3 (court was "fully persuade[d]" by *Swift*, but found Government met the *Sequoia* standard).

In both *Amico* and *Piacentile*, the Second Circuit determined that the Government's motion to dismiss exceeded the *Sequoia Orange* standard. Importantly, case-specific factors played key roles in each of these Court decisions. In both *Amico* and *Piacentile*, the Government had already negotiated settlements between the defendants and array of other plaintiffs, providing support for identified valid purposes of dismissal, including ending duplicative litigation and deterring parasitic lawsuits.

Pertaining to Relator's D-RI case, the Government also overstates the First Circuit's "preference" for *Swift in Nasuti ex rel. v. Savage Farms, Inc.* "I note only that, unlike the magistrate judge, I find the Swift rationale more persuasive. Our minor doctrinal difference is of no moment in the circumstances." In *Nasuti*, the First Circuit also reviewed both *Swift* and *Sequoia Orange*, as well as case-specific factors. *U.S. ex rel. Nasuti v. Savage Farms, Inc.*, Civ. 12-30121-

GAO (D. Mass. March 27, 2014).

Consistent with these Second and First Circuit precedents, Relator respectfully requests that the Court apply the same flexible approach in considering this § 3730(c)(2)(A) motion.

F. An Ongoing Second Circuit Case Supports Judicial Oversight of Agencies.

State and private plaintiffs have challenged the Department of Commerce's decision to reinstate a question regarding citizenship status in the 2020 census. *State of New York, et al., v. United States Department of Commerce*, 215 (SDNY, July 26, 2018). One line of argument in the Government's efforts to dismiss the matter was its claim that the Court lacked the authority for judicial review under the Administrative Procedures Act (APA) P.L.79-404 60 Stat. 237 (1946) and other statutes. The Court disagreed. "…Defendants insist that this Court lacks jurisdiction even to consider Plaintiffs' claims. As the Court will explain, however, that contention flies in the face of decades of precedent from the Supreme Court, the Second Circuit, and other courts. That precedent makes clear that, while deference is certainly owed to the Secretary's decisions, courts have a critical role to play in entertaining challenges…" "More specifically, the APA authorizes a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . .arbitrary [or] capricious," "contrary to constitutional right," "in excess of statutory jurisdiction," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A)-(D). id.

GOVERNMENT FAILS *SEQUOIA'S* RATIONAL RELATION TEST

Under *Sequoia Orange*, the Government must identify "a valid government purpose" and show a "rational relation between dismissal and accomplishment of the purpose." In both this case and the D-RI action, the Government's rationale for seeking dismissal is the same:(1) Government's financial/ resource burden from ongoing litigation, which could be better applied elsewhere; (2) Government's claim that Relator's allegations lack merit; and, (3) Government's claim that Relator's behavior creates serious concerns. Relator avers that all three of the Government's unsupported

rationales for dismissal are invalid and arbitrary.

A. Government Provides no Factual Support for Claims that Relator's Cases Lack Merit.

As with the *qui tam* Defendants in their motions to dismiss, the government now claims, without providing factual support, that Relator's well-pleaded allegations lack merit. The Government's commentary is limited to generalized, conclusory statements: "concerns about the merits of Relator's theories of liability"; "the *qui tam* case does not merit prosecution"; "determined that the theory is deeply flawed".

Without providing any specificity or factual support, the Government's conclusory statements carry no weight. After four-plus years of investigation, the Government could easily provide the Court specificity regarding Relator's allegations and its investigation but fails to do so. As with the Defendants' prior motions, Relator avers that the government has avoided direct challenge due to the truth and accuracy of the allegations. On this basis alone, the Government's motion to dismiss should be denied.

B. With Clear Case Merit, Government's "Resource Concerns" are Baseless.

Beyond its claim of "unfettered discretion", the Government's main argument for dismissal pertains to the purported extensive financial and resource burden it expects to bear in continued litigation. In Relator's *qui tam* cases, which allege vast taxpayer and Government financial harm, the Government's resource rationale is closely linked to the merits of the cases. By intentionally failing to provide any specificity or factual support for its claims that Relator's cases "lack merit", the Government's "resource" argument should be quickly dispensed by the Court. Rather, with these factually specific, large-scale *qui tam* cases being meritorious, the potential return to the Government and taxpayers is vastly greater than the amount of resources likely to be employed by our Government.

The Government goes to great lengths to exaggerate its resource requirements related to these *qui tam* cases. First, the Government falsely states that its burden is escalated by the "scope,

breadth and opacity" of the Relator's allegations. The Government falsely claims that the Relator has "drawn no distinction among the PBMs or drug manufacturers", which would lead to "vast and intrusive discovery". Ironically, the Government is most concerned with the burden on CMS, whose regulatory and oversight shortcomings in Part D have been a major factor contributing to the long-standing and ongoing alleged scheme. SAC ¶¶ 11, 69, 279, 293-4.

Relator has presented to the Government and the Court highly specific allegations which provides a clear path to targeted discovery and the efficient use of both private and Government resources. Relator's cases focus on specific pharmaceutical products with clear evidence of severe pricing and "service fee" abuse: 14 specific major drugs in several therapeutic categories in the SDNY action and 8 specific multiple sclerosis (MS) drugs in the D-RI action. Given the centralized/national nature of Medicare Part D program and the contractual arrangements between the Manufacturer and Defendant parties, these cases are uniquely positioned for targeted discovery and litigation. Furthermore, the legal requirement that the Manufacturer Defendants maintain "itemized" records, by individual drug product, for PBM Defendant "service fee" payments, PBM Defendant services provided and their FMV determination enables highly-efficient investigation of the central "kickback" allegations. SAC ¶ 294-5.

Initially, DOJ appeared to agree with Relator's straightforward view of the case and its investigative path. In the final conference call with DOJ, on December 12, 2013, just prior to the initial D-RI filing, Dr. Borzilleri expressed his concern about his own non-insider status and his lack of access to closely-guarded Defendant information. In allaying his concerns, Assistant U.S. Attorney (AUSA) Zachary Cunha stated: "Don't worry about that, we will get the contracts, see how much they are getting paid and what they are getting paid for…it should be a relatively quick investigation." Borzilleri Decl. ¶ 5.

Finally, the Government falsely cites Relators "rejection" of DOJ's eleventh-hour request

to "transfer or consolidate" his two *qui tam* cases as both unnecessarily increasing the Government burden and indicative of illicit intent. In reality, Relator made a carefully considered decision based upon the public interest and judicial efficiency. Borzilleri Decl. ¶ 19.

Relator had no interaction with DOJ in either jurisdiction between its March 2018 non-intervention decisions and early September 2018. Suddenly, just before Labor Day, DOJ from SDNY and D-RI requested a conference call with Relator. In a brief 5-10-minute call on September 4, 2018, DOJ requested that Relator consider "consolidation or transfer", while providing minimal commentary. DOJ admitted that it had not contacted the Court in either jurisdiction or any Defendants regarding the issue.

Relator carefully considered DOJ's request over the next week. Given the established efficient Court briefing schedules in both jurisdictions, as well as case-specific issues (especially first-to-file and particularity concerns), Relator determined that DOJ's late-dated request would be highly disruptive, especially given the lack of Court involvement. See Borzilleri Decl. ¶ 19 regarding the September 4, 2018 conference call with DOJ and related matters. With an acute interest in judicial economy, Relator remains open to transfer or consolidation, if deemed appropriate by the Court.

Of note, after the SDNY *qui tam* filing in October 2015, DOJ aggressively pursued transfer of the SDNY case back to D-RI in discussions with Relator's counsel. Dr. Borzilleri expressed his willingness to consider transfer, with assurances of active investigation of the new Defendant drugs in D-RI. On February 16, 2016, Dr. Borzilleri had his "Relator Interview" with SDNY, which included teleconference participation by DOJ from D-RI. As the interview drew to a close, Relator's counsel mentioned potential transfer of the SDNY action to D-RI. Rebecca Martin[3], then the co-Chief of the SDNY Civil Frauds Unit, curtly replied: "Oh, that is not going to happen". There was no further

[3] On September 7, 2016, Rebecca Martin left SDNY to join McDermott, Will and Emery, LLP, which is now counsel for Manufacturer Defendant Amgen in this action.

discussion of the issue. As the interview closed, Relator's counsel discussed plans to assist SDNY in formulating Civil Investigative Demands ("CIDs) to be sent to the SDNY Defendants. Borzilleri Decl. ¶ 11.

C. Government Co-opts Defendants' Ad Hominem Attacks on the Relator.

The Government has adopted, as a basis for dismissal, the Defendants' ad hominem attacks on the Relator, based upon unsubstantiated allegations in ongoing employment litigation as a basis for dismissal. After 15 years of unblemished service, Dr. Borzilleri was told by his employer, Shepherd Kaplan Krochuk's (SKK) of its plans for his termination, without a stated cause, just days after his two *qui tam* cases were unsealed in April 2018. When Dr. Borzilleri mentioned whistleblower retaliation statutes to SKK management, he was suddenly terminated when served with a lawsuit in early May 2018. In September 2018, Dr. Borzilleri's prompt counterclaims, including whistleblower retaliation and wrongful termination, resulted in a denial of SKK's motion to dismiss and the case entered discovery. In December 2018, Dr. Borzilleri filed a motion to dismiss SKK's initial complaint, which is now pending in Massachusetts Superior Court. Dr. Borzilleri expects to be fully exonerated in this employment litigation. Dr. Borzilleri's recent motion to dismiss, SKK's opposition and Dr. Borzilleri's reply is provided as Exhibit 2.

Contrary to the Government's claims that Dr. Borzilleri has been "evasive", he promptly and directly responded to DOJ's concerns regarding his conduct. On November 16, 2018, DOJ filed a letter to the SDNY Court, publicly announcing it was considering filing 31 U.S.C. § 3730 (c)(2)(A) motions both in SDNY and D-RI. On November 28, 2018, DOJ sent Relator a letter requesting "clarification" regarding his conduct pertaining to securities trading and *qui tam* seal requirements while at his former employer, SKK. On December 6, 2018, Relator provided a detailed response to DOJ in both SDNY and D-RI. See Exhibit 3 for DOJ's request to Relator and his reply.

In addition to directly addressing DOJ's concerns regarding his conduct, Dr. Borzilleri

requested DOJ's assistance in securing Security and Exchange Commission (SEC) investigations regarding his own trading activities, as well as SEC-related concerns regarding the behavior of SKK and the *qui tam* Defendants.[4] Dr. Borzilleri pledged full cooperation and transparency in any SEC investigations. DOJ did not respond to Relator's December 6, 2018 reply.

RELATOR'S LONG-STANDING EFFORTS TO ADDRESS U.S. DRUG PRICING ABUSE

A. Relator's Extensive Public Interest Efforts Prior to *Qui Tam* Filing.

In early 2013, Dr. Borzilleri determined that collusion of an uncertain nature (prior to his uncovering the alleged "service fee" scheme) between certain drug manufacturers and the dominant PBMs was at the center of widespread burgeoning anti-competitive US brand drug price increases. Dr. Borzilleri quickly commenced investigation, which culminated in a series of detailed written reports, in the winter and spring of 2013, which highlighted his initial investigative findings.

In February 2013, Dr. Borzilleri began an extensive effort to engage federal authorities in investigation of pharmaceutical and PBM business practices. Dr. Borzilleri particularly hoped to engage the Federal Trade Commission (FTC) and the closely-affiliated Antitrust Division of the Department of Justice, as well as the Office of Inspector General at the Department of Health and Human Services (OIG at HHS). Dr. Borzilleri also forwarded his written reports to an array of non-governmental healthcare experts, including major media healthcare reporters, Wall Street analysts, and a wide array of other organizations.

To his surprise, Dr. Borzilleri's efforts were largely ignored by Government officials, the major media and other healthcare experts.

Prior to filing his initial D-RI *qui tam* action, Dr. Borzilleri informed the DOJ of his

[4] As per the SACs in both *qui tam* actions, in April 2018 Relator filed a SEC Whistleblower complaint regarding the *qui tam* Defendants, alleging violation of SEC "material" reporting requirements pertaining to "service fees". Other than notice of receipt of the complaint, Dr. Borzilleri has had no contact with the SEC. Dr. Borzilleri recently filed a second complaint with the SEC regarding the *qui tam* Defendants.

extensive unsuccessful engagement efforts. Following his January 2014 initial complaint filing, Relator had a "Relator interview" with the DOJ in D-RI on June 10, 2014. At the meeting, Assistant U.S. Attorney (AUSA) Zachary Cunha asked Dr. Borzilleri to forward his pre-*qui tam* email communications and several of his pre-*qui tam* reports to DOJ. On June 23, 2014, Dr. Borzilleri forwarded DOJ, by email, two of his investigative reports. The later of the two, a 37-page report from March 2013, is provided as Exhibit 4.

In the same email, Dr. Borzilleri also sent DOJ a document with 82-pages of his pre-*qui tam* effort emails. See Exhibit 5. The document includes both emails to and from FTC staff. As documented in the emails, Dr. Borzilleri had several conference calls with FTC in the spring/summer of 2013, but no follow-up thereafter. Dr. Borzilleri was unable to engage the Anti-Trust Division of the Department of Justice or the OIG at HHS.

Dr. Borzilleri's frustration in engaging Government investigation was the central factor in his decision to file an atypical non-insider *qui tam* action once he uncovered, thoroughly investigated and verified the "service fee" scheme in the summer/fall of 2013. As per federal statutes, a *qui tam* filing required Government investigation.

B. Relator's Extensive Efforts to Assist Government's *Qui Tam* Investigations.

After filing his *qui tam action*, Dr. Borzilleri continued his efforts to assist Government investigation. On February 13, 2014, Relator provided DOJ an extensive investigative outline as part of a disclosure statement, which included detailed discussion of allegations, as well as a wide array of initial potential discovery requests and witnesses. See Exhibit 6.

Over the next several years, Dr. Borzilleri provided a wide array of additional investigative information to DOJ, via both extended analytical reports and email communications. Major analytical reports included analyses of false claims and kickback pathways, AKS safe harbors, Medco Health financial statements, Diplomat Specialty Pharmacy and fair market value (FMV), Part D catastrophic

subsidies and other key issues. The additional analytical information uniformly verified the *qui tam* "service fee" scheme. Exhibit 7 includes an array of the detailed analytical reports sent by Relator to DOJ.

In addition, with DOJ's encouragement, the Relator directly provided an array of investigative information to DOJ via email (especially during the early stages of its investigations), including real-time evidence (due to Relator's unique position as a professional healthcare investment analyst) of escalating pricing and "service fee" fraud.

By early 2015 it became increasingly apparent to Dr. Borzilleri, that D-RI DOJ was not pursuing major areas of investigation, evidence and key witnesses which he provided. By then, Dr. Borzilleri had determined that the price collusion "service fee" scheme was accelerating and expanding, including new unforeseen evidence of abuse beyond the narrow "specialty" drug segment (only 1-2% of US prescriptions) into the far broader "traditional" U.S. brand drug marketplace.

On February 27, 2015, Dr. Borzilleri and counsel had an update call with D-RI AUSA Zachary Cunha and Sanjay Bhambhani from the Civil Division regarding a DOJ investigation extension request. Based on his new investigative findings, Dr. Borzilleri queried DOJ about amending his D-RI complaint to add additional drug products and defendants. DOJ discouraged the Relator from amending his D-RI action, saying "its investigation would remain focused on the multiple sclerosis category, regardless of an amendment". Borzilleri Decl. ¶ 8. As will be discussed later, on the same call DOJ also notified Relator, for the first of several times, that it was struggling to identify a "viable false claims path" pertaining to his allegations.

On a September 25, 2015 conference call, AUSA Zachary Cunha from the DOJ in RI informed the Relator and counsel that "intervention" in the D-RI *qui tam* case was "unlikely", primarily because "CMS was not supportive" of the case. Borzilleri Decl. ¶ 9. Mr. Cunha stated that CMS viewed the allegations as a "regulatory issue" that were "not amenable to the False Claims Act".

Mr. Cunha stated that subpoenas in D-RI had been "put on hold, pending ongoing discussions with CMS". Dr. Borzilleri responded that he was not surprised by CMS' lack of support, given the regulatory and oversight shortfalls discussed in the complaint. Mr. Cunha responded that CMS was their "client". Relator responded that he thought the "American public was DOJ's client in the case." Dr. Borzilleri stated to Mr. Cunha that if the Government viewed it as a "regulatory" issue and not "fraud", "that was fine" - then CMS should "fix it" to stop any further harm. Mr. Cunha stated that DOJ hoped to file a non-intervention decision with the RI Court "soon" "in a matter of months" to "get out of the way" so that Relator could pursue the matter as "a public policy issue". In closing the call, Dr. Borzilleri informed Mr. Cunha that he had nearly completed a new *qui tam* document regarding additional pharmaceutical products. Dr. Borzilleri informed Mr. Cunha that he remained open to filing an amended complaint in D-RI and would forward a draft of the document for his review.

Dr. Borzilleri directly emailed a draft of the new *qui tam* document to Mr. Cunha on September 28, 2015. Mr. Cunha did not reply to the email and never provided any feedback.

The DOJ in D-RI ultimately filed its non-intervention decision with the RI Court nearly two-and-a-half years later in March 2018, after several Relator challenges to DOJ investigation extension requests.

On October 6, 2015, in the public interest, the Relator filed his second *qui tam* action in SDNY. Due to the potential for greater resources, and SDNY's history of independence, Relator was hopeful for a better investigative result. Although initial signs of a separate investigation in SDNY were promising, DOJ quickly began coordinating its efforts in both jurisdictions. Ultimately, the same investigative deficiencies became apparent in both jurisdictions.

Due to escalating public harm from accelerating US drug price increases and clear deficiencies in the DOJ investigations, Relator began challenging DOJ investigative extensive requests in both jurisdictions in early 2017.

GOVERNMENT'S DISMISSAL ATTEMPT IS PRETEXTUAL, ARBITRARY AND CAPRICIOUS

Even if the Court determines that Government's rationale is valid under the *Sequoia Orange* standard, its motion should be denied because the dismissal attempt is "pretextual, arbitrary and capricious". In his Declaration, Dr. Borzilleri discusses key interactions with DOJ over the past four-plus years. Both Relator himself and counsel participated in virtually all key DOJ phone calls and meetings.

A. Government Failed to Intervene Despite Verifying the Straightforward Scheme.

Early in investigation, both D-RI and SDNY, DOJ admitted to Relator that PBM "service fee" payments from the Manufacturer Defendants to the PBM manufacturers are standardly based upon "percent of revenue" contracts, linked to "list" (AWP ("Average Wholesale Price) or WAC ("Wholesale Acquisition Cost") prices and price increases. SDNY AUSAs Cristine Phillips and Li Yu made the admission in a conference call with Relator and counsel on March 31, 2017. A similar admission was made in several conference calls with D-RI AUSA Zachary Cunha. Borzilleri Decl. ¶¶ 12-13, 15.

As such, consistent with the SACs in both jurisdictions, for most Defendant drugs, the Manufacturer Defendants were admittedly paying the PBM Defendants, about five-fold more in "services fees" for each dispensed prescription compared to a decade ago. In the most extreme instances, the PBMs Defendants are now commonly receiving many hundreds or more than a thousand dollars for each monthly prescription, often for simply shipping, from a remote mail order pharmacy, a chronic "specialty" therapy to a stably-treated patient.

B. DOJ in SDNY Provided a False Rationale for Non-Intervention.

Relator did not have a final conference call with the RI DOJ regarding its non-intervention decision. However, on March 8, 2018, Dr. Borzilleri and counsel did have a final conference call with SDNY AUSA Cristine Phillips. During the call, Dr. Borzilleri requested the rationale for the non-

intervention decision. The only specific reply from Ms. Phillips was that DOJ thought the "service fee" contractual arrangements between the Manufacturer and PBM Defendants were protected by the Group Purchasing Organization (GPO) anti-kickback safe harbor. During the call, Ms. Phillips also encourage Relator to consider voluntarily dismissing the *qui tam* action. Borzilleri Decl. ¶ 18.

Dr. Borzilleri immediately knew Ms. Phillip's claim regarding the GPO safe harbor was not accurate, based upon information provided to DOJ in the complaint and a separate detailed analysis. SAC ¶¶ 305, 674-88. In Exhibit 8, also see the Relator analytical report sent to SDNY DOJ on September 7, 2016.

Verifying the lack of merit of Ms. Phillips' basis for non-intervention, neither the Manufacturer nor PBM Defendant groups, in either SDNY or D-RI, have argued in their motions to dismiss that the GPO safe harbor protects them from Relator's "kickback" allegations.

C. Government Refuted No Relator Allegations and Provided No Alternative Explanation.

Throughout its investigation, DOJ never refuted any of Relator's allegations nor his ongoing investigative findings. Rather, escalating evidence provided to DOJ from Relator's ongoing investigation uniformly verified the allegations and the expanding "service fee" scheme causing severe public harm.

As DOJ's intent to not intervene in either jurisdiction became clear, Relator posed a direct question to DOJ in both D-RI and SDNY: "If the "service fee" scheme is not the cause of massive US Defendant drug price increases, does the DOJ have any alternative theories?" The answer to that question from the DOJ in SDNY and RI was consistent, surprising and disappointing. In both instances, DOJ indicated that that it did not know the answer and it was not part of their investigation. Borzilleri Decl. ¶ 16.

D. Government Quickly Shifted Investigation Away from Manufacturer Defendants.

The primary legal liability for the fair market value (FMV) payment of bona fide service

fees (BFSFs) falls squarely on the drug manufacturers, not the PBMs. SAC ¶ 44. In fact, due to this clear distinction, Relator's initial complaint in D-RI in January 2014 only named the multiple sclerosis (MS) drug manufacturers as Defendants. In May 2014, Relator filed a first amended complaint in D-RI, adding the PBM Defendants due to increasing recognition of PBM Part D certification requirements and the "kickback" liability for both parties in the fee transactions. See D-RI SAC generally.

Due to these clear legal parameters, Relator was surprised when the DOJ in both the D-RI and SDNY indicated early in their investigations that their focus was primarily on the PBM Defendants and not the Manufacturer Defendants. This DOJ investigative focus also made little sense because the Manufacturer Defendants were garnering the majority of financial benefit from the vast price increases enabled by the fraudulent scheme. SAC ¶¶ 11, 69, 279. Borzilleri Decl. ¶¶ 8, 12, 16.

E. CMS Investigative Obstruction and Conflicts of Interest.

Relator alleges that regulatory deficiencies by CMS in the Part D program have been a major factor contributing to the long-standing "service fee" scheme in both *qui tam* matters. SAC ¶¶ 163, 279, 293-4.

Both the DOJ in SDNY and RI disclosed to Relator that CMS has not been *"supportive"* of the allegations and investigation in these *qui tam* cases. First, as stated previously, in late September 2015, the DOJ in D-RI informed Relator that intervention in the case was "not likely" because CMS was not supportive of the allegations. Borzilleri Decl. ¶ 9.

During an August 17, 2017 update conference call with Relator, the SDNY DOJ reiterated that CMS remained *"unsupportive"* of the investigation in both *qui tam* matters. On the call SDNY AUSA Cristine Phillips stated that "CMS was not helpful". She said there were "lots of agency concerns". She said there were very few cases that went forward when CMS was not supportive. She admitted that she had reviewed data from the Defendants, but not from CMS. Borzilleri Decl. ¶ 16.

These DOJ interactions suggest that CMS significantly hindered the Government's investigation of Relator's *qui tam* cases.

Relator has also expressed concerns to DOJ regarding potential leadership conflicts-of-interest at CMS pertaining to these *qui tam* investigations. From February 2015 through early 2017, Andrew Slavitt, a recent former senior executive of PBM Defendant UnitedHealth Group, was the Acting Administrator of CMS. Since early 2018, the Secretary of Health and Human Services (HHS) has been Alex Azar, a recent former senior executive of SDNY Manufacturer Defendant Eli Lilly.

The Government's motion to dismiss further escalates Relator concerns regarding CMS' influence regarding these *qui tam* cases. The Government repeatedly highlights its concerns regarding CMS' potential "resource burden" related to a potential Relator investigation. "Responding to such requests will impose a significant burden…most importantly, on components of CMS." SDNY DOJ motion ¶ page 15.

GOVERNMENT FAILED TO PURSUE KEY ALLEGATIONS, EVIDENCE AND WITNESSES

A. Government Failed to Pursue the Central Kickback Allegations.

As per the SACs in both jurisdictions, straightforward and severe "kickbacks" are the central allegations in Relator's *qui tam* actions. "Claims tainted by AKS violations are ineligible for reimbursement and, thus, false." *U.S. ex rel. Kester v. Novartis, et.al.*, 1:11-CV-08196-CM-JCF (SDNY, Nov 2011).

Despite being the central allegations, DOJ failed to aggressively pursue the "kickback" path in its investigations. Rather, DOJ's investigative focus was on Part D submissions, especially plan sponsor Direct and Indirect Remuneration (DIR) reports, which offered little potential to identify fraud. SAC ¶¶ 293-4. As clearly described in all filed complaints (and other information provided to DOJ), Relator alleges that the PBM Defendants are NOT reporting these excessive "service fees" in Part D submissions, especially in DIR reports by their wholly-owned plan sponsors. Further, the PBM

Defendants have numerous opportunities to hide manufacturer fee payments in other subsidiaries (PBM, specialty pharmacy and others), which don't have direct Part D reporting requirements. SAC ¶ 293.

The Government's failure to aggressively pursue the "kickback" allegations was counter to DOJ's own stated view of the case at outset. The Relator initially contacted DOJ in the District of Massachusetts (D-MA) via email on October 22, 2013. The email introduction stated that "the drug manufacturer's pricing practices have violated the Stark Anti-kickback laws..." See Exhibit 8 for pre-*qui tam* filing emails between Relator and DOJ in D-MA in late 2013. Relator and counsel had a preliminary call with the D-MA DOJ the next day, October 23, 2013. After reviewing Relator's information, DOJ provided feedback to Relator and counsel on November 14, 2013. On both conference, calls, USAMA George Henderson stated that he viewed the potential *qui tam* filing as primarily a "kickback" case. On the November 14, 2013 call, the D-MA DOJ then referred Relator to Zachary Cunha in the D-RI where the action was filed in early January 2014. Borzilleri Decl. ¶¶ 2-3.

On February 27, 2015, Relator and counsel had a conference call with D-RI AUSA Zachary Cunha and Sanjay Bhambhani from the DOJ Civil Frauds Section. Borzilleri Decl. ¶ 8. On the call, DOJ informed Relator that it was having trouble defining a "viable false claims path". DOJ stated that plan sponsor DIR reports did not indicate any excessive "service fees". Relator responded that he was not surprised – PBM Defendant DIR reports were unlikely to identify the fraud. In fact, if they were properly reporting the "fees" as discounts in DIR reports, severe Part D price inflation would not have occurred. Dr. Borzilleri reiterated that investigation of the *qui tam* cases would likely require direct inquiry of Defendant transactions, contractual relationships and services. SAC ¶ 296. On that call and other DOJ calls, Dr. Borzilleri repeatedly queried DOJ as to why it was not predominantly investigating the straightforward "kickback" allegations. DOJ never gave a direct reply.

In frustration, Dr. Borzilleri reviewed the following with Mr. Cunha in a conference call,

either on September 30, 2016 or March 28, 2017. (Borzilleri Decl. ¶ 10.):

> **Dr. Borzilleri:** "So, based on the contracts you have reviewed, you have confirmed that the majority of "service fee" arrangements are structured as "percent of revenue", linked to drug "list" prices and price increases?
> **AUSA Cunha:** Yes/confirmed.
> **Dr. Borzilleri:** And we know that for most of the Defendant MS drugs that prices and US sales have greatly increased, while prescription volume has been plummeting?
> **AUSA Cunha:** Yes/confirmed.
> **Dr. Borzilleri:** So then, the PBMs are getting huge increases in "service fees" while patients treated, prescription volume and related service support needs are sharply declining?
> **AUSA Cunha:** Yes/confirmed.
> **Dr. Borzilleri:** So, if these massive fee payments are not "kickbacks", what is a "kickback"?
> **AUSA Cunha:** No reply.

DOJ's failure to aggressively pursue the central "kickback' allegations in Relator's actions is counter to DOJ's publicly-stated priorities. On the December 21, 2018, DOJ released its False Claim Act Statistics for fiscal 2018. The DOJ Press Release states: "Department continued to place great importance on enforcing the safeguards contained within the Anti-Kickback Statute (AKS). This law was enacted to ensure that clinical decisions and medical services are provided to patients based on their medical needs and not on the improper financial considerations of providers. Congress has made clear that claims submitted to federal health care programs in violation of the AKS are "false" claims for purposes of the False Claims Act." *Justice Department Recovers Over $2.8 billion from False Claims Act Cases in Fiscal Year 2018*, December 21, 2018.

B. Government Failed to Investigate Relator's Part D Catastrophic Fraud Allegations.

In both *qui tam* cases, the Relator alleges that wide-ranging fraud by the Defendants regarding Part D plan sponsor Catastrophic cost-sharing requirements has markedly escalated in recent years along with massive Defendant "specialty" drug price increases. Relator alleges that fraudulent forgiveness of the PBM Defendants' 15% Catastrophic exposure was essential for perpetuating the "service fee" scheme related to massive Manufacturer Defendant "specialty" drug price increases. In fact, the Relator avers that the financial magnitude of Catastrophic fraud in recent years may far exceed

the direct "service fee" fraud in many instances. SAC ¶¶ 32-33, 347-357, 395-444. While DOJ's investigations were underway, based upon newly public information from the Medicare Payment Advisory Commission (MedPAC) regarding Part D Catastrophic Subsidies, Relator provided a detailed analytical report to DOJ in both SDNY and D-RI. The Relator Catastrophic report sent to SDNY, dated March 17, 2016, is included in Exhibit 7.

Despite the detailed information provided by Relator, DOJ admitted that it never directly investigated these severe Catastrophic allegations. When queried regarding the Catastrophic allegations on an August 9, 2016 conference call with Relator, SDNY AUSA Cristine Phillips surprisingly stated that DOJ "had not thought it through", without providing any additional commentary. Borzilleri Decl. ¶ 12. Regarding the Catastrophic issue, in a phone call with Relator on March 28, 2017, D-RI AUSA Zachary Cunha stated that he "had not looked at it" but that DOJ did not see "factual support". Mr. Cunha further stated that "they had enough on their plate with other allegations." Borzilleri Decl. ¶ 14.

C. In its Combined Investigations, Government Deposed only ONE Defendant Witness.

The combined DOJ in SDNY and D-RI repeatedly admitted deposing only a single Defendant employee, an unnamed person from Express Scripts, in its four-plus year purportedly "careful and thorough" investigation. Borzilleri Decl. ¶ 17. DOJ would not provide any specific feedback to Relator after this deposition. Furthermore, this single deposition occurred in late January 2018, when DOJ in both jurisdictions had already repeatedly communicated to Relator that it would not intervene in either action. As such, the single Defendant deposition appears to have been pretextual to DOJ's simultaneous non-intervention decisions in SDNY and D-RI in March 2018.

D. Government Failed to Pursue a Wide Array of Witnesses Provided by Relator.

Relator's attendance and first-hand feedback from a one-of-a-kind industry conference in early October 2013, entitled "Fair Market Value of Bona Fide Service Fees", was a key catalyst in his

decision to file his *qui tam* actions. SAC ¶¶ 452-89. All *qui tam* complaints filed with DOJ regarding both cases include extensive Relator first-hand commentary from the conference, in addition to the names/contact information for presenters and attendees. SAC ¶¶ 452-89 and SAC Exhibit 14.

To Relator's surprise, DOJ in both jurisdictions repeatedly admitted that conference witnesses were not interviewed or deposed as part of either investigation. Despite repeated Relator inquiry in update conference calls, DOJ provided no viable rationale for the lack of pursuit. Borzilleri Decl. ¶¶ 12-13, 15.

Again, DOJ's failure to pursue insider witnesses from this unique FMV conference was inconsistent with Relator's early interactions with the D-MA DOJ in October 2013 prior to filing the initial D-RI case. In the email interactions and phone discussions in October 2013 with D-MA, the Relator highlighted the witnesses from the conference as a rapid path for verification of his investigative findings. Following Relator's initial phone discussion with DOJ in D-MA, he forwarded DOJ, via email, a 105-page investigative report, which included his extensive first-hand commentary from the conference. The email also included the agenda and presentation slides from the event. See Exhibit 9 for the email communications with DOJ in D-MA. See Exhibit 9 for Relator's investigative report sent to DOJ on October 23, 2013. Also see Borzilleri Decl. ¶¶ 2-3.

Relator has also accumulated a wide array of additional potential witnesses (current and former Defendant employees, Pharmaceutical and PBM industry consultants, Wall Street analysts, healthcare reporters, etc.), many of which can quickly verify the straightforward "service fee" scheme. DOJ expressed no interest in pursuing these many witnesses throughout its four-plus years of so-called "careful and thorough" investigation.

E. Government Ignored Major New Evidence since its March 2018 Non-Intervention.

Relator has provided major new evidence supportive of his allegations in his SAC filed in both jurisdictions and in his recent SDNY opposition motion. Key new evidence includes Defendant

disclosures of "service fee" contract rates (SAC ¶¶ 177-197), low manufacturer rebate rates for Defendant products (SAC ¶¶ 198-213), minimal PBM profits from manufacturer rebates (Opp. ¶ page 3), and most importantly, Defendant product Medicare Part D spending, pricing and claims data (Opp. ¶¶ pages 3, 45-50). All this additional evidence supports and verifies the "service fee" scheme.

Nonetheless, the Relator has had no investigative interaction with DOJ since its non-intervention decisions regarding both his SDNY and D-RI *qui tam* actions in March 2018. Rather, DOJ now appears determined to unjustifiably prevent the Relator from efficiently pursuing these well-supported *qui tam* cases in the Court.

CONCLUSION

For the reasons above, Relator respectfully submits that the Court should deny the Government's 31 U.S.C. § 3730(c)(2)(A) motion to dismiss this *qui tam* action, without need for a hearing. However, if the Court deems the Government's rationale for seeking dismissal to be adequate, Relator respectfully requests discovery, additional briefing and an evidentiary hearing regarding the matter.

Dated: January 11, 2019

Respectfully submitted,

/s/ Mary Ann H. Smith
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CERTIFICATE OF SERVICE

I, Mary Ann H. Smith, hereby certify that, on January 11, 2019, I caused a copy of the foregoing notice of motion, along with the supporting papers, in *U.S.* et al. ex rel. *Borzilleri v. AbbVie, Inc.* et al., 18 Civ. 7881 (JMF) to be served, by ECF and e-mail, upon counsel for coordinating counsel for defendants at:

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and upon all other counsel by ECF.

Dated: January 11, 2019

/s/ *Mary Ann H. Smith*
Mary Ann H. Smith